STATE OF SOUTH DAKOTA CLASS SPECIFICATION

Class Title: Laboratory Quality Assurance Class Code: 40663

Coordinator

A. Purpose:

Works with the department head, section leaders, and staff on the implementation and monitoring of a quality control system for the entire laboratory to comply with accreditation guidelines.

B. Distinguishing Feature:

The <u>Laboratory Quality Assurance Coordinator</u> defines, writes, implements, and monitors the quality control system for the laboratory.

The <u>Senior Microbiologist</u> is responsible for completing, analyzing, and monitoring testing activities in one or more specialized sections of a microbiology laboratory such as quality control for water quality, virology, bacteriology, serology, immunology, parasitology, mycology, or mycobacteriology; and ensures that proper procedures are followed by coworkers, monitors quality control methods, validates new test procedures, and participates in and/or directs method development.

C. Functions:

(These are examples only; any one position may not include all of the listed examples nor do the listed examples include all functions which may be found in positions of this class.)

- 1. Develops and administers the laboratory quality assurance program for serology, virology, clinical pathology, bacteriology, molecular diagnostic, histology, necropsy, and receiving to ensure testing accuracy and consistency.
 - a. Reviews client complaints, survey the staff, and review laboratory records to determine the critical areas for quality control.
 - b. Updates and unifies the standard operating procedures (SOP) for each section in the laboratory by meeting with section leaders and evaluating SOP's.
 - c. Evaluates quality control data to determine trends and issues and develops corrective action plans to address any issues.
 - d. Reviews, updates, and approves quality assurance plans.
 - e. Schedules and facilitates regular quality assurance committee meetings.
 - f. Reviews quality control documentation and preventative maintenance records.
 - g. Reviews procedure manuals and updates manuals as new procedures are added.
 - h. Assists in the preparation of documentation for accreditation reviews.
 - i. Monitors the quality of the laboratory water by establishing a check system for culture plates.
 - j. Develops and provides training to section staff regarding laboratory quality control programs.
- 2. Coordinates and manages the laboratory proficiency testing to ensure personnel are proficient in performing testing.
 - a. Coordinates the distribution and results of the USDA proficiency tests to ensure the laboratory personnel meet all certification requirements.
 - b. Institutes internal proficiency testing for areas not governed by the USDA.
 - c. Contacts vendors to order proficiency tests and communicates the results.

- d. Coordinates internal audits in various sections of the laboratory.
- 3. Develops and maintains the laboratory quality control data system to ensure the needs of the laboratory are met.
 - a. Graphs and charts the quality control information to identify and react to laboratory trends.
 - b. Works with section leaders to establish a monthly quality control check and how the information will be documented.
 - c. Implements corrective action plans for sections not meeting quality control standards.
- 4. Represents the laboratory nationally by assisting in the development of national accepted outline of procedures to audit and assess laboratory control programs.
- 5. Performs other work as assigned.

D. Reporting Relationships:

Typically reports to a department head and provides work direction to Senior Microbiologists, Microbiologists, Laboratory Technicians, Laboratory Aides, Chemists, Senior Chemists, and students.

E. Challenges and Problems:

Challenges include developing an effective quality control program for the laboratory; motivating laboratory personnel to comply with the quality control program; and organizing, evaluating, summarizing, and predicting trends from the quality control data.

Typical problems include determining result errors and where it occurred in the testing method and ensuring errors do not reoccur and are not part of a quality control problem.

F. Decision-making Authority:

Decisions include developing an acceptable quality control program, if problems in the laboratory are the result of quality control errors or not, corrective action plans to resolve quality control issues, and if SOP's are written accurately and in compliance with developed criteria.

Decisions referred include major changes to laboratory functions, because of quality control issues and approval of major changes in the laboratory's quality control program that could have a large impact on the laboratory.

G. Contact with Others:

Monthly contact with laboratory section leaders to implement and monitor the laboratory quality control program and the national quality assurance committee to establish standardized quality control manuals.

H. Working Conditions:

Works in a laboratory setting with dangerous chemicals and infectious pathogens.

I. Knowledge, Skills and Abilities:

Knowledge of:

- the principles and practices of serology, virology, clinical pathology, bacteriology, molecular diagnostic, histology, biology, immunology, organic chemistry, and other subjects related to microbiology;
- medical technology;
- accreditation standards specific to the laboratory section;
- general and technical test quality variation, specificity, sensitivity, and validation procedures;
- technical information and literature resources in life sciences.

Ability to:

- work safely with dangerous and contagious materials and specimens;
- operate computers;
- communicate information clearly and concisely, both orally and in writing;
- establish and maintain effective working relationships with others.